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EXAMINER	
HUSON, MONICA ANNE	
ART UNIT	PAPER NUMBER
1791	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/787,079	ROSENBERG ET AL.	
	Examiner	Art Unit	
	MONICA A. HUSON	1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,7-9 and 11-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,7-9 and 11-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the Remarks filed 1 March 2010.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5, 7-9, and 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dabal et al. (U.S. Patent 4,072,551), in view of Klimesch et al. (U.S. Patent 5,073,379). Regarding Claim 1, Dabal shows that it is known to carry out a method for producing tablets by melt extrusion (Column 8, lines 1-44; Column 10, lines 3-13), in which an extrudable pharmaceutical mixture is heated and extruded in the form of a continuous product strip, wherein, in a first stage, the still deformable product strip is compressed to a continuous tablet belt, the individual tablets in the belt being connected together by product webs (Figure 5, element 82, 83; Figure 6B), in a second stage, downstream of the first stage, the tablet belt is allowed to cool to form a solidified tablet belt (Figure 5, printing unit; It is noted that ambient cooling will take place along the transport sections.), in a third stage, downstream of the second stage, the tablets are mechanically singulated in a continuous process (Figure 5, unitizing unit), wherein a force with a component perpendicular to the plane of the tablet belt is allowed to act on the tablet belt for singulation of the tablet (Figure 5, unitizing unit; It is noted that the force exerted by the roller will have at least two components.), and then the singulated tablets are transported further to a fourth stage downstream of the said third stage where the singulated tablets are subsequently deflashed (Column 32, lines 13-18).

Dabal does not show extruding a mixture containing a pharmaceutically active ingredient. Klimesch et al., hereafter "Klimesch," show that it is known to carry out a method of extruding a mixture containing a pharmaceutically active ingredient (Column 2, lines 40-63). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Klimesch's melt extrusion composition that includes a pharmaceutically active ingredient during Dabal's molding process in order to avoid having to add the active ingredient at a later stage after extrusion. Dabal does not show a directional force that diverts the tablet belt in a downward direction from a transport plane to a tangential plane at an angle to the transport plane. Klimesch '379 shows that it is known to carry out a method wherein the perpendicular force component is generated by diverting the solidified tablet belt downwardly out of its transport plane to an angled tangential plane (Figure 1: singulated tablets are diverted downward in a tangential plane at an angle to the transport (horizontal) plane; Column 2, lines 61-67). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Klimesch '379's diverting force to tabulate Dabal's belt in order to most efficiently achieve the unitizing operation.

Regarding Claim 3, Dabal shows the process as claimed as discussed in the rejection of Claim 1 above, including a method wherein a force with a component parallel to the plane of the tablet belt is allowed to act on the tablet belt for singulation of the tablets (Figure 5, unitizing unit; It is noted that the force exerted by the roller will have at least two components.).

Regarding Claim 5, Dabal shows the process as claimed as discussed in the rejection of Claims 1 and 2 above, Regarding Claim 5, Dabal shows the process as claimed as discussed in the rejection of Claim 3 above, including a method wherein the parallel force component is generated by exerting a traction force on the solidified tablet belt (Figure 5, unitizing unit; It is noted that the force exerted by the rollers will include some traction force.).

Regarding Claim 12, Dabal shows that it is known to have an apparatus for producing tablets (Figure 5), comprising at least one extruder means for heating a

pharmaceutical mixture (Column 8, lines 1-44; Column 10, lines 3-13); means for shaping a tablet belt from said extruded heated pharmaceutical mixture arranged downstream of said extruder, said extruder means forming a tablet belt comprising individual tablets connected by a product web (Figure 5, element 82, 83; it is interpreted that although there is not a large web space between the tablets, the tablets are connected by a web between each tablet, even if the web space is very small.; Figure 6B); first transport means for said tablet belt comprising means for cooling the extruded tablet belts and which is arranged downstream of said shaping means (Figure 5, printing unit; It is noted that ambient cooling will take place along the transport sections.), and means for singulating and deflashing said tablets, wherein said means for singulating and deflashing said tablets comprise at least one singulating means arranged downstream of said first transport means and at least one deflashing means arranged downstream of said singulating means and spatially separate therefrom (Figure 5, unitizing unit; Column 32, lines 13-18; It is noted that the transport means is the tension force that is generated by the two rollers acting together on the tablet belt.). Dabal does not show extruding a mixture containing a pharmaceutically active ingredient. Klimesch shows that it is known to carry out a method of extruding a mixture containing a pharmaceutically active ingredient (Column 2, lines 40-63). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Klimesch's melt extrusion composition that includes a pharmaceutically active ingredient during Dabal's molding process in order to avoid having to add the active ingredient at a later stage after extrusion. Dabal does not show a directional force that diverts the tablet belt in a downward direction from a transport plane to a tangential plane at an angle to the transport plane. Klimesch '379 shows that it is known to carry out a method wherein the perpendicular force component is generated by diverting the solidified tablet belt downwardly out of its transport plane to an angled tangential plane (Figure 1: singulated tablets are diverted downward in a tangential plane at an angle to the transport (horizontal) plane; Column 2, lines 61-67). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention

was made to use Klimesch '379's diverting force to tabulate Dabal's belt in order to most efficiently achieve the unitizing operation.

Regarding Claim 7, Dabal shows the apparatus as claimed as discussed in the rejection of Claim 12 above, including a machine wherein the singulating means comprises at least one rotatable roller (Figure 5, unitizing unit).

Regarding Claim 8, Dabal shows the apparatus as claimed as discussed in the rejection of Claim 7 above, including a machine wherein the singulating means comprises two counter-rotating rollers which can be pressed against one another (Figure 5, unitizing unit).

Regarding Claim 9, Dabal shows the apparatus as claimed as discussed in the rejection of Claim 12 above, including a machine wherein the singulating means comprises at least one embossed roller (Column 22, lines 58-63).

Regarding Claim 11, Dabal shows the apparatus as claimed as discussed in the rejection of Claim 12 above, including a machine wherein a second transport means is provided between the singulating means and the deflashing means and the deflashing means comprises a shaking or vibrating unit (Column 30, lines 12-19; Column 32, lines 13-18; It is noted that by suggesting that the tablets are amenable to online testing throughout their production, Dabal implies that the tablets are transported from the unitizing to the deflashing operation in a predetermined fashion.).

Regarding Claim 13, Dabal et al., hereafter "Dabal," show that it is known to carry out a method for producing tablets by melt extrusion (Column 8, lines 1-44; Column 10, lines 3-13), in which an extrudable pharmaceutical mixture is heated and extruded in the form of a continuous product strip, wherein, in a first stage, the still deformable product strip is compressed to a continuous tablet belt, the individual tablets in the belt being connected together by product webs (Figure 5, element 82, 83; Figure 6B), in a second stage, downstream of the first stage, the tablet belt is allowed to cool to form a solidified tablet belt (Figure 5, printing unit; It is noted that ambient cooling will take place along the transport sections.), in a third stage, downstream of the second stage, the tablets are mechanically singulated in a continuous process (Figure 5, unitizing unit), and then

the singulated tablets are transported further to a fourth stage downstream of the said third stage where the singulated tablets are subsequently deflashed (Column 32, lines 13-18), including a method wherein a force with a component perpendicular to the plane of the tablet belt is allowed to act on the tablet belt for singulation of the tablet (Figure 5, unitizing unit; It is noted that the force exerted by the roller will have at least two components.). Dabal does not show a directional force that diverts the tablet belt in a downward direction from a transport plane to a tangential plane at an angle to the transport plane. Klimesch '379 shows that it is known to carry out a method wherein the perpendicular force component is generated by diverting the solidified tablet belt downwardly out of its transport plane to an angled tangential plane (Figure 1: singulated tablets are diverted downward in a tangential plane at an angle to the transport (horizontal) plane; Column 2, lines 61-67). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Klimesch '379's diverting force to tabulate Dabal's belt in order to most efficiently achieve the unitizing operation.

Regarding Claim 14, Dabal shows the process as claimed as discussed in the rejection of Claim 13 above, but he does not show extruding a mixture containing a pharmaceutically active ingredient. Klimesch shows that it is known to carry out a method of extruding a mixture containing a pharmaceutically active ingredient (Column 2, lines 40-63). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Klimesch's melt extrusion composition that includes a pharmaceutically active ingredient during Dabal's molding process in order to avoid having to add the active ingredient at a later stage after extrusion.

Regarding Claim 15, Dabal shows the process as claimed as discussed in the rejection of Claim 13 above, including a method wherein singulating and said melt extrusion speed are substantially similar (Column 22, lines 9-19).

Regarding Claim 16, Dabal shows the process as claimed as discussed in the rejection of Claim 13 above, including a method wherein a speed of a breaking roller is configured to match a speed of a transport belt (Figures 3, 4A; Column 21, lines 42-49; Column 22, lines 5-25; Column 23, lines 9-19).

Regarding Claim 17, Dabal shows the process as claimed as discussed in the rejection of Claim 13 above, including a method wherein the melt extrusion and singulating are continuous (Column 12, lines 66-68; Column 13, lines 1-8).

Regarding Claims 18-19; Dabal shows the process as claimed as discussed in the rejection of Claim 13 above, including a method wherein the cooling renders the continuous tablet belt resistant to bending or deformation (Figures 5; It is being interpreted that ambient cooling renders the belt able to be transported independently without bending or deforming out of line with the rollers and subsequent processing stations).

Response to Arguments

Applicant's arguments filed 1 March 2010 have been fully considered but they are not persuasive.

Applicant contends that Klimesch does not describe diverting a solidified tablet belt in a downward direction from a transport plane to a tangential plane and further that Klimesch only shows diverting finished tablets. This is not persuasive because, as claimed, the force which diverts the solidified tablet belt in a downward direction is the same force which singulates the tablets. In other words, the force acts on the tablet belt, causing it to start to divert and also causing singulation. As claimed, there is no distinction between a force which causes the belt to divert and also a force which singulates the tablets, or a requirement that the belt is diverted prior to singulation. As claimed, the tablets are “mechanically singulated in a continuous process” with only one named force which accomplishes both diversion and singulation. With regard to Klimesh, it is believed that the perpendicular element of the force applied by elements 5 causes diversion of the belt at the right-most end of the elements, followed almost immediately by singulation therefrom.

Applicant contends that Dabal does not describe diverting a solidified tablet belt in a downward direction from a transport plane to a tangential plane, and applicant also notes that Dabal’s finished tablets are “apparently floating”. This is not persuasive because Dabal was not cited to show the tablet diversion (see Klimesch, above), and

the examiner submits that Dabal's drawing depiction of the finished tablets is to show the general concept of the finished individual tablets and was not intended to imply that the finished tablets are not subjected to the force of gravity.

Applicant contends that both Dabal and Klimesh involve the concepts of concurrent forming and unitizing, but that the present invention does not use these concepts. This is not persuasive because the instant claims do not preclude the use of the concepts of concurrent forming and unitizing.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONICA A. HUSON whose telephone number is (571)272-1198. The examiner can normally be reached on Monday-Friday 7:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on 571-272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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